

Valerie James  
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NEW ZEALAND

2280 '99 SEP 13 A9 54

August 31<sup>st</sup> 1999

Documents Management Branch (H.F.A. 305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville MD 20852  
U.S.A.

Dear Sir/Madam

**PROPOSED HEALTH CLAIM LINKING CONSUMPTION  
OF SOY PROTEIN AND CORONARY HEART DISEASE:  
63 FED.REG.62977 (Nov 10, 1998)**

I have been informed that Protein Technologies Inc., has provided supplemental material (July 9<sup>th</sup> 1999) for consideration by the Dockets Management Branch in respect of the above proposed health claims. New studies have also been submitted by the American Soybean Association.

I assume that all new evidence presented by industry will be made available, by public notice, for public comment. If not I request that prior to publishing a final ruling, the F.D.A. includes in its evaluation a recently released ANZFA (Australia and New Zealand Food Authority) 40 page document especially the following statements:

"Phytoestrogens" ANZFA document, March 1999 (pp 4,5,29,28)

"Phytoestrogens appear to be able to alter the thyroid hormone levels in adults and in infants. The mechanism of action may be a direct competitive inhibition of thyroid peroxidase which is essential for the production of thyroid hormones, and also may be an indirect reduction of circulating free thyroxine levels-. In normal individuals these effects may be compensated by the existing homeostatic mechanisms, but for individuals in whom iodine intake is low or the thyroid function is compromised, phytoestrogens are a potential hazard."

"While it is clear that phytoestrogens pose a potential hazard to the consumer of soy foods, they are also suggested to have benefits. The hazard consists of the potential changes in hormonal levels in adults and infants, and includes effects arising from oestrogen agonism; antioestrogenic activity; reduction in the thyroid function and alteration of sex-specific patterns of early development."

98P-0683

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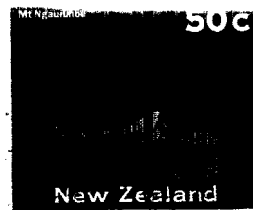
The ANZFA assessment was prepared by Dr Luba Tomaska, Principal Toxicologist, ANZFA, with the assistance of an expert panel consisting of:  
Dr F. Cumming; Mr F. Dalais; Dr P. Hartmann; Prof. J. Mann; Dr P. McVeigh;  
Dr Pat Tuohy; Prof. M. Wahlquist.

Yours sincerely

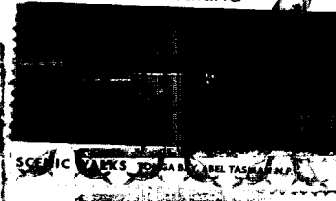
A handwritten signature in black ink that reads "Valerie James." The signature is written in a cursive style with a large initial "V" and a long, sweeping underline.

Valerie James

cc Susan Pilch  
Linda Kahl



\$1.00 New Zealand



Administrator, Dockets Management Branch (HFA-305)  
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